

PATENT COOPERATION TREATY

OCT 25 2001

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

To: KEVIN S. LEMACK
NIELDS & LEMACK
176 E. MAIN STREET
SUITE 8
WESTBORO, MA 01581

Date of Mailing
(day/month/year)

22 OCT 2001

Applicant's or agent's file reference

559P017-PCT

IMPORTANT NOTIFICATION

International application No.

PCT/US00/24892

International filing date (day/month/year)

12 SEPTEMBER 2000

Priority Date (day/month/year)

13 SEPTEMBER 1999

Applicant

BRIDGE PHARMA, INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US

Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

CELIA CHANG

Telephone No. (703) 308-1235

Garye Bridges for

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

REC'D 25 OCT 2001

WIPO PCT

Applicant's or agent's file reference 559P017-PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/24892	International filing date (day/month/year) 12 SEPTEMBER 2000	Priority date (day/month/year) 13 SEPTEMBER 1999
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 31/445; C07D 409/04 and US Cl.: 514/324, 546/202		
Applicant BRIDGE PHARMA, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

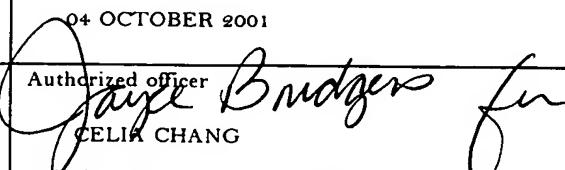
2. This REPORT consists of a total of 3 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 28 FEBRUARY 2001	Date of completion of this report 04 OCTOBER 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  CELIA CHANG
Facsimile No. (703) 305-3230	Telephone No. (703) 308-1235

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/24892

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed☒ the description:pages 1-20, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of _____☒ the claims:pages 21-24, as originally filedpages NONE, as amended (together with any statement) under Article 19pages NONE, filed with the demandpages NONE, filed with the letter of _____☒ the drawings:pages NONE, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of _____☒ the sequence listing part of the description:pages NONE, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. ☒ The amendments have resulted in the cancellation of:☒ the description, pages NONE☒ the claims, Nos. NONE☒ the drawings, sheets/fig NONE5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/24892

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	<u>1-20</u>	YES
	Claims	<u>NONE</u>	NO
Inventive Step (IS)	Claims	<u>NONE</u>	YES
	Claims	<u>1-20</u>	NO
Industrial Applicability (IA)	Claims	<u>1-20</u>	YES
	Claims	<u>NONE</u>	NO

2. citations and explanations (Rule 70.7)

Claims 1-20 meet the criteria set out in PCT Article 33(2) and PCT Article 33(4), because the prior art did not disclosed the particular isolated stereomer nor did the prior art indicated any inoperability in industrial application.

Claims 1-20 lack an inventive step under PCT Article 33(3) as being obvious over Polivka (CA 113:40470) or Polivka (CA 112:216595) in view of Kofler et al. (Japan. Chem. Soc). Claims 1-20 claimed specific stereoisomers of formula of claim 1. Compounds of formula of claim 1 are known and recognized to have chiral centers. Ordinary skilled persons in the art knowledgeable of the chiral center will be motivated to carry out routine laboratory procedure to separate and purify the known mixture thus obtain the individual stereoisomer or diastereomer as taught by the reference of Japan. Chem. Soc.

Applicants' response filed on 20 September 2001 contained arguments that claim 1 do not have chiral centers, thus, an obviousness concluded from chiral separation does not apply and that the claimed compounds do not have the side effect of the racemates. Please note that claim 1 are drawn to "racemates" which are the results of "chiral" centers. The "side-effect" as argued by applicants were only disclosed in the testing methods for the various side effects "without" data supporting such arguments.

_____ NEW CITATIONS _____

NONE

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 17 July 2001 (17.07.01)	
International application No. PCT/US00/24892	Applicant's or agent's file reference 559P017-PCT
International filing date (day/month/year) 12 September 2000 (12.09.00)	Priority date (day/month/year) 13 September 1999 (13.09.99)
Applicant ABERG, A., K., Gunnar et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 28 February 2001 (28.02.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer H. Zhou Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

JAN 29 2001

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

LEMACK, Kevin, S.
Nields & Lemack
Suite 8
176 E. Main Street
Westboro, MA 01581
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 16 January 2001 (16.01.01)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 559P017-PCT	
International application No. PCT/US00/24892	International filing date (day/month/year) 12 September 2000 (12.09.00)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 13 September 1999 (13.09.99)
Applicant BRIDGE PHARMA, INC. et al	

- The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
- An asterisk(*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
- The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

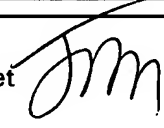
<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
13 Sept 1999 (13.09.99)	60/153,566	US	28 Dece 2000 (28.12.00)
15 Apr 2000 (15.04.00)	60/197,363	US	28 Dece 2000 (28.12.00)
15 Apr 2000 (15.04.00)	60/197,905	US	28 Dece 2000 (28.12.00)
15 Apr 2000 (15.04.00)	60/197,906	US	28 Dece 2000 (28.12.00)
15 Apr 2000 (15.04.00)	60/197,985	US	28 Dece 2000 (28.12.00)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Jocelyne Rey-Millet



Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT APR 2 2001

From the INTERNATIONAL BUREAU

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:

LEMACK, Kevin, S.
Niels & Lemack
Suite 8
176 E. Main Street
Westboro, MA 01581
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 22 March 2001 (22.03.01)		
Applicant's or agent's file reference 559P017-PCT		IMPORTANT NOTICE
International application No. PCT/US00/24892	International filing date (day/month/year) 12 September 2000 (12.09.00)	
		Priority date (day/month/year) 13 September 1999 (13.09.99)
Applicant BRIDGE PHARMA, INC. et al		

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:

AU,KP,KR,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE,AG,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,BZ,CA,CH,CN,CR,CU,CZ,DE,DK,DM,DZ,EA,EE,EP,ES,
FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,
MN,MW,MX,MZ,NO,NZ,OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,
The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
22 March 2001 (22.03.01) under No. WO 01/19367

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer J. Zahra Telephone No. (41-22) 338.83.38
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